

AVAILABILITY OF MODIFIED TEXT

NOTICE IS HEREBY GIVEN that the Dental Board of California has proposed modifications to the text of section 1005, in Title 16 Cal. Code Reg. which were the subject of a regulatory hearing on May 14, 2004. A copy of the modified text is enclosed. Any person who wishes to comment on the proposed modifications may do so by submitting written comments on or before July 19, 2004.

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DENTAL BOARD OF CALIFORNIA

Modified Text

Changes to the originally proposed language are shown by double underline for new text and double strike-through for deleted text.

Amend Section 1005 to read:

§ 1005. Minimum Standards for Infection Control

(a) As Definitions of terms used in this section:

(1) ~~“Universal Standard precautions” is an approach to infection control according to which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other blood borne pathogens.~~ is a set of combined precautions that include the major components of universal precautions (designed to reduce the risk of transmission of blood borne pathogens) and body substance isolation (designed to reduce the risk of transmission of pathogens from moist body substances). Similar to universal precautions, standard precautions are used for care of all patients regardless of their diagnoses or personal infectious status.

(2) “Critical instruments” are surgical and other instruments used to penetrate soft tissue or bone.

(3) “Semi-critical instruments” are surgical and other instruments that are not used to penetrate soft tissue or bone, but contact oral tissue.

(4) “Non-critical instruments and devices” are instruments and devices that contact intact skin.

(5) “Low-level disinfection” is the least effective disinfection process, kills some bacteria, viruses and fungi, ~~It~~ but does not kill bacterial spores or mycobacterium tuberculosis var bovis, a laboratory test organism used to classify the strength of disinfectant chemicals.

(6) “Intermediate-level disinfection” kills mycobacterium tuberculosis var bovis ~~that indicates less resistant organisms such as hepatitis B and HIV are also killed,~~ indicating that many human pathogens are also killed, but does not necessarily kill spores.

(7) “High-level disinfection” kills some, but not necessarily all bacterial spores. This process kills mycobacterium tuberculosis var bovis, ~~and other~~ bacteria, fungi, and viruses.

(8) All germicides must be used in accordance with intended use and label instructions.

(9) “Sterilization” kills all forms of microbial life.

(10) “Personal Protective Equipment” includes items such as gloves, masks, protective eyewear and protective attire (gowns/labcoats) which are intended to prevent exposure to blood and body fluids.

(11) “Other Potentially Infectious Materials” (OPIM) means any one of the following: (A) human body fluids such as saliva in dental procedures and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (B) any unfixed tissue or organ (other than intact skin) from a human (living or dead); (C) HIV-containing cell or tissue cultures, organ culture and blood, or other tissues from experimental animals.

(b) Licensees ~~with one or more employees~~ shall comply with infection control precautions mandated by the California ~~Occupational Safety and Health Administration~~ Division of

Occupational Safety and Health (Cal-DOSH). All licensees shall comply with the following minimum precautions to minimize the transmission of pathogens in health care settings:

- ~~(1) Universal precautions shall be practiced in the care of all patients~~
- ~~(2) Medical exam gloves shall be worn whenever there is potential for contact with blood, blood contaminated saliva, or mucous membranes. Sterile gloves shall be worn in connection with surgical procedures involving soft tissue or bone. Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolants/irrigants are deemed to be sterile when delivered using a device or process that has a Food and Drug Administration (FDA) marketing clearance for delivery of sterile coolants/irrigants to the patient. Delivery of sterile coolants/irrigants shall be in accordance with the manufacturer's directions.~~

(c) All licensees shall comply with and enforce the following minimum precautions to minimize the transmission of pathogens in health care settings:

- (1) Standard precautions shall be practiced in the care of all patients.
- (2) A written protocol shall be developed by the licensee for proper instrument processing, operatory cleanliness, and management of injuries.
- (3) A copy of this regulation shall be conspicuously posted in each dental office.

Personal Protective Equipment:

- ~~(3) Health care workers shall wash hands and put on new gloves before treating each patient. Antimicrobial soap shall be used to wash hands for surgical procedures. Health care workers shall wash hands after removing and discarding gloves after treatment of each patient or before leaving the operatory. Gloves shall not be washed before or after use.~~
- ~~(4) Health care workers shall wear surgical facemasks in combination with and either chin length plastic face shields or ~~surgical masks and~~ protective eyewear when treating patients whenever there is potential for splashing or spattering of blood or OPIM. After each patient, and during patient treatment if applicable, masks shall be changed if moist or contaminated. After each patient, face shields and protective eyewear shall be cleaned and disinfected, if contaminated.~~
- ~~(5) Health care workers shall wear reusable or disposable gowns protective attire when their clothing or skin is likely to be soiled with blood or ~~other bodily fluids~~ OPIM. Gowns must be changed daily or between patients if it should become moist or visibly soiled. Protective attire must be removed when leaving laboratories or areas of patient care activities. Reusable gowns shall be laundered in accordance with Cal-DOSH Bloodborne Pathogens Standards.~~
- ~~(6) Protective attire must be removed when leaving the laboratories and work areas.~~
- ~~(7) Items or surfaces such as, but not limited to, light handles which are impossible to clean and disinfect, shall be protected with impervious barriers. Between patients, the covering must be removed, discarded and replaced with clean covering.~~
- ~~(8) Splash shields shall be used in dental laboratories.~~

Hand Hygiene:

- (6) Health care workers shall wash contaminated or visibly soiled hands with soap and water and put on new gloves before treating each patient. If hands are not visibly soiled or contaminated an alcohol based hand rub may be used as an alternative to soap and water.
- ~~(9)~~ (7) Healthcare workers who have exudative lesions or weeping dermatitis of the hand shall refrain from all direct patient care and from handling patient care equipment until the condition resolves.

Gloves:

(8) Medical exam gloves shall be worn whenever there is a potential for contact with mucous membranes, blood or OPIM. Gloves must be discarded upon completion of treatment and before leaving laboratories or areas of patient care activities. Healthcare workers shall perform hand hygiene procedures after removing and discarding gloves. Gloves shall not be washed before or after use.

~~(10) Needles shall be recapped only by using the scoop technique or a mechanical device designed for holding the needle sheath, or a mechanical device which eliminates the need for two-handed capping. Needles shall not be bent or broken prior to disposal. Disposable needles, syringes, scalpel blades and/or other sharp items and instruments shall be placed into puncture resistant containers for disposal.~~

Sterilization and Disinfection:

~~(11)~~ (9) Heat stable critical and semi-critical instruments shall be cleaned and sterilized before use by using steam under pressure (autoclaving), dry heat, or chemical vapor. Cal/EPA registered FDA cleared chemical sterilants/disinfectants shall be used for sterilization of heat-sensitive critical items and for high-level disinfection of heat-sensitive semi-critical items.

~~(12) Heavy duty utility gloves shall be worn to process instruments before sterilization or high level disinfection.~~

(10) Critical and semi-critical instruments or containers of critical and semi-critical instruments sterilized by a heat or vapor method shall be packaged or wrapped before sterilization if they are not to be used immediately after being sterilized. These packages or containers shall remain sealed unless the instruments within them are placed onto a setup tray and covered with a moisture impervious barrier on the day the instruments will be used and shall be stored in a manner so as to prevent contamination.

(11) All high-speed dental hand pieces, low-speed hand piece components used intraorally, and other dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips, shall be heat-sterilized between patients.

(12) Single use disposable instruments (e.g. prophylaxis angles, prophylaxis cups and brushes, tips for high-speed evacuators, saliva ejectors, air/water syringe tips) shall be used for one patient only and discarded.

(13) Needles shall be recapped only by using the scoop technique or a protective device. Needles shall not be bent or broken for the purpose of disposal. Disposable needles, syringes, scalpel blades or other sharp items and instruments shall be placed into sharps containers for disposal according to all applicable regulations.

~~(13) Critical and semi-critical instruments shall be packaged before sterilization if they are not to be used immediately and remain sealed until used.~~

~~(14) Proper functioning of the sterilization cycle shall be verified at least weekly through use of a biological indicator (such as spore test).~~

~~(15) Countertops and dental unit surfaces shall be cleaned with disposable towels followed by a Cal/EPA intermediate level disinfectant between patients. Cal/EPA low level disinfectants shall be used for visibly soiled areas such as floors, walls and other housekeeping surfaces.~~

(14) Proper functioning of the sterilization cycle shall be verified at least weekly through the use of a biological indicator (such as a spore test). Test results must be maintained for 12 months.

Sterilization:

~~(15) Proper functioning of the sterilization cycle shall be verified at least weekly through the use of a biological indicator (such as a spore test). Test results must be maintained for 12 months.~~

Irrigation:

~~(14)~~ (15) Sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolants/irrigants must be delivered using a sterile delivery system.

Facilities:

(16) If items or surfaces likely to be contaminated are difficult to clean and disinfect they shall be protected with disposable impervious barriers.

~~(15) Intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate level disinfectant before manipulation in the laboratory and before placement in the patient's mouth.~~

(17) Clean and disinfect all clinical contact surfaces that are not protected by impervious barriers using a Cal-EPA registered, hospital grade low- to intermediate-level disinfectant after each patient. The low-level disinfectants used shall be labeled effective against HBV and HIV. Use disinfectants in accordance with the manufacturer's instructions. Clean all housekeeping surfaces (e.g. floors, walls, sinks) with a detergent and water or a Cal-EPA registered, hospital grade disinfectant.

~~(16) — All high speed dental handpieces, low speed handpiece components used intraorally, and other dental unit attachments such as reusable air/water syringe tips and ultrasonic scaler tips shall be heat sterilized between uses.~~

(18) Dental unit water lines shall be anti-retractable. At the beginning of each workday, dental unit lines shall be purged with air, or flushed with water for at least two (2) minutes prior to attaching handpieces, scalers and other devices. The dental unit line shall be flushed between each patient for a minimum of twenty (20) seconds.

~~(18) Anti retraction devices in dental unit water lines shall be installed and maintained.~~

(19) Contaminated solid waste shall be disposed of according to applicable local, state, and federal environmental standards.

Lab Areas:

~~(19) The dental unit line shall be flushed between each patient.~~

(20) Splash shields and equipment guards shall be used on dental laboratory lathes. Fresh pumice and a disinfected, sterilized, or new ragwheel shall be used for each patient. Devices used to polish, trim or adjust contaminated intraoral devices shall be disinfected or sterilized.

~~(17) Single use disposable instruments (e.g. prophylaxis, angles, prophylaxis cups and brushes, tips for high speed evacuators, saliva ejectors, air/water syringe tips) shall be used for one patient only and discarded appropriately.~~

(21) Intraoral items such as impressions, bite registrations, prosthetic and orthodontic appliances shall be cleaned and disinfected with an intermediate-level disinfectant before manipulation in the laboratory and before placement in the patient's mouth. Such items shall be thoroughly rinsed prior to placement in the patient's mouth.

(21) At the beginning of each workday, dental unit lines shall be purged with air or flushed

~~with water for at least two (2) minutes prior to attaching handpieces, scalers and other devices.~~

~~(22) Contaminated solid waste shall be disposed of according to appropriate local, state and federal environmental standards.~~

~~(23) A written protocol shall be developed for proper instrument processing, operator cleanliness, and management of injuries. A copy of this regulation shall be conspicuously posted in each dental office.~~

~~(e)~~ (d) The Board shall review this regulation annually.

NOTE: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1680, Business and Professions Code.